Summary for Public Disclosure

Submitter: Hiroyuki Matsui
Matsushita Electric Industrial Co., Ltd.
Health & Heating Products Division
800, Tsutsui-Cho
Yamatokoriyama, Nara 639-1188
Japan

Tel: (0743) 56-9865
Fax: (0743) 56-9052

Official Correspondent: David L. West, Ph.D.
Vice President, Quintiles Consulting
Phone: (301) 272-3113
Fax: (301) 272-0004
E-mail: david.west@quintiles.com

Date summary was prepared

December 29, 2000

Name(s) of the device

Trade name: Panasonic Tele-Homecare System

Common name: Physiologic Monitoring System

Classification name: §870.1130 Noninvasive blood pressure measurement system.

§870.2910 Radiofrequency physiological signal transmitter and receiver.

Identification of predicate device(s)

Equivalency is based on the HealthTech Services Corporation HANC Network (K952979) and the American Telecare Aviva Model SLX (K993550).

Description / Intended Use

The Panasonic Tele-Homecare System is a medical device that provides vital sign and other physiologic parameter data of a patient obtained and recorded at a location remote from a healthcare practitioner and transmits them to the practitioner. The system consists of

(1) Patient terminal
(2) Physiologic parameter sensors or instruments (selected by healthcare practitioner)
(3) Doctor Terminal software
(4) Server software
(5) Administrative Terminal software

The physiologic parameter sensors, or instruments, selected by the healthcare practitioner operate in conjunction with the patient terminal located in the patient's home, a hospital room, or other health care facility. The patient terminal, in turn, communicates to the healthcare practitioner through a network server. The patient terminal connects to the server via a conventional telephone line or through the internet.

Indications for Use

The Panasonic Tele-Homecare System is a physiologic monitoring system. The system collects, accumulates, and transmits patient vital sign and other physiological data from a patient who may be remote from the healthcare practitioner to the practitioner and provides communication between the patient and practitioner via video, audio or e-mail through the Patient and Doctor terminals. The following physiologic information can be monitored on an intermittent (non-continuous) basis:

- Temperature (oral)
- Blood pressure
- Blood glucose
- Blood oxygen (O2 sat)
- Electrocardiogram (ECG)
- Auscultation (body sounds) via electronic stethoscope
- Respiratory Peak flow
- Body Weight
- Urine test

Comparison of device characteristics to predicate

Comparison to Predicate Devices			
DEVICE NAME	**Tele-Homecare System**	**Hanc Network**	**Aviva System, Model SLX**
MANU-FACTURER	Matsushita Electric Industrial Co., Ltd.	Healthtech Services Corp.	American Telecare, Inc.
510(k) Number	-	K952979	K993550
Product Code	74 DXN: System, Measurement, Blood-Pressure, Non-Invasive 74 DRG: Transmitters And Receivers, Physiological Signal, Radiofrequency	74 DXN: System, Measurement, Blood-Pressure, Non-Invasive	74 DRG: Transmitters And Receivers, Physiological Signal, Radiofrequency
CLASSIFICATION	§870.1130 Noninvasive blood pressure measurement system. §870.2910 Radiofrequency physiological signal transmitter and receiver.	§870.1130 Noninvasive blood pressure measurement system.	§870.2910 Radiofrequency physiological signal transmitter and receiver.
Physiologic Sensors Included **Key:** **☐ (not included)** **☒ (included)**	☒ Blood Pressure/Pulse ☒ ECG ☒ Thermometer ☒ Stethoscope ☒ Pulse Oximeter ☒ Blood Glucose ☒ Weight Scale	☒ Blood Pressure/Pulse ☒ ECG ☒ Thermometer ☒ Stethoscope ☒ Pulse Oximeter ☐ Blood Glucose ☒ Weight Scale	☒ Blood Pressure/Pulse ☐ ECG ☐ Thermometer ☒ Stethoscope ☐ Pulse Oximeter ☒ Blood Glucose ☐ Weight Scale
Other Functions	Capability for manual entry of also respiratory peak flow, and urine data. Voice/video communication. Close-up views of body areas.	Captures a video image, reminds patient to take medication, manually entered data	Voice/video communication; Transmission of information through a central station Close-up views of body areas.

Non-clinical testing

As the Panasonic Tele-Homecare System utilizes patient sensors that have already received 510(k) clearance, the testing to demonstrate substantial equivalence for this product heavily relies on:

- Testing to meet the product requirements and functional specifications;
- Verification that the physiologic data received by the patient monitors are stored properly; and,

- Verification that the data is transmitted to the healthcare practitioner in a manner that maintains the security and integrity of the data.

System testing includes testing to the product and software functional and performance requirements, as well as sending a signal to the patient terminal communication port for each sensor, viewing the data via the patent terminal, then transmitting the data to view on the physician's terminal. The testing performed demonstrates that the functional requirements and specifications have been met, and the signal data that was received by the patient terminal and transmitted to the physician was identical. In conclusion, the test results demonstrate substantial equivalence.

Conclusion

Matsushita Electric Industrial Co., Ltd. concludes that the Panasonic Tele-Homecare System is equivalent to the HealthTech Services Corporation HANC Network (K952979) and the American Telecare Aviva Model SLX (K993550). Collectively, the two predicate devices from Healthtech Services Corp. and American Telecare, Inc. provide all of the features and functions of the Panasonic Tele-Homecare system. The additional sensors or instruments of the Panasonic device individually compared to either of these predicates do not raise any new types of safety or effectiveness questions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 5 2001

David L. West, Ph.D.
Matsushita Electric Industrial Co., Ltd.
c/o Quintiles Consulting
1801 Rockville Pike, Suite 300
Rockville, MD 20852

Re: K004050
Trade Name: Panasonic Tele-Homecare System
Regulatory Class: II (two)
Product Code: 74 MWI
Dated: December 29, 2000
Received: December 29, 2000

Dear Dr. West:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might

have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K004050
Device Name: **Panasonic Tele-Homecare System**

Indications For Use:

The Panasonic Tele-Homecare System is a physiologic monitoring system. The system collects, accumulates, and transmits patient vital sign and other physiological data from a patient who may be remote from the healthcare practitioner to the practitioner and provides communication between the patient and practitioner via video, audio or e-mail through the Patient and Doctor terminals. The following physiologic information can be monitored on an intermittent (non-continuous) basis:

- **Temperature (oral)**
- **Blood pressure**
- **Blood glucose**
- **Blood oxygen (O2 sat)**
- **Electrocardiogram (ECG)**
- **Auscultation (body sounds) via electronic stethoscope**
- **Respiratory Peak flow**
- **Body Weight**
- **Urine test**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K004050

(Optional Format 3-10-98)